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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,697	01/27/2000	Bernard Dujon	3495.0111-11	1254

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EXAMINER
KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
1636	20

DATE MAILED: 05/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/492,697	Applicant(s) DUJON ET AL.	
	Examiner S. Kaushal	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-60* is/are pending in the application.

4a) Of the above claim(s) *38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 January 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's response filed on 11/19/01 has been acknowledged.

Claims 38-60 are pending.

Claims 38-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

In response to the Petition Decision on Paper No.17 (01/03/02), claims 45-60 have been examined in this office action to include the linking claims 45-48 and 52-55.

▶ *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (http://www.uspto.gov) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-47, 50-54 and 57-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a recombinant mammalian chromosome and a mammalian cell comprising the recombinant chromosome wherein the chromosome comprising a Group I intron encoded endonucleases site selected from the group consisting of Class I I-endonuclease sites, Class II I-endonuclease sites,Class III I-endonuclease sites, Class IV I-endonuclease sites and Class V I-endonuclease sites.

The invention as claimed encompasses any and all endonucleases sites selected from Group-I-intron-encoded endonuclease sites. At best the specification only discloses endonucleases sites for Class I (I-SceI, I-SceIV, I-PanI) and Class II (I-TevI). The specification fails to disclose any endonuclease sites that represent Class III (I-PpoI), Class IV (I-TevII) and Class V (I-TevIII) endonucleases sites (spec. page 27 and fig-6). In addition, the instant specification discloses that Class III, IV and V endonuclease sites are not represented by any typical structural motifs (spec. page 27, lines 13-21). The specification fails to disclose any consensus nucleotide sequences and/or structural motifs that represent a particular Class of Group-I encoded endonuclease sites that exist in nature. Furthermore it is clear that endonucleases of Class I (I-SceI, I-SceIV, I-PanI) are structurally and functionally distinct endonucleases which cut structurally unique endonuclease sites. The art at the time of filing teaches that Group-I introns form a structural and functional groups of introns with wide spread irregular distribution among very diverse organisms and genetic systems (Dujon Gene 82:91-114, 1989, see abstract). The general knowledge in the art concerning Group I Intron encoded endonuclease does not provide any indication as how the structure of one Class of endonucelases is representative of other Classes having concordant or discordant functions and/or restriction sites (Dujon Gene 82:115,-118 1989. see page 17, table-I). Besides Class I I-endonuclease sites (I-SceI, I-SceIV, I-PanI) the specification fails to disclose a representative number of species for Class II I-endonuclease sites,Class III I-endonuclease sites, Class IV I-endonuclease sites and Class V I-endonuclease sites.

In additon, the possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention *(Pfaff v. Wells Electronics, Inc 48 USPQ2d 1641, 1646 (1998)*. In addition, one cannot describe what

one has not conceived. The claims directed to a mammalian FGF's were found to be un-patentable due to lack of written description for that broad class. The specification provided only the bovine sequence. (*See Fiddes v. Baird, 30 USP2d 1481 at 1483*). Furthermore, the disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. *(see In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000)*. According to these facts, one skill in the art would conclude that applicant was not in the possession of the claimed genus because a description of only one member of this genus is not representative of the variants of genus and is insufficient to support the claim.

Claims 45-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a recombinant mammalian chromosome comprising an endonuclease site selected from Class I I-endonuclease sites, wherein the Class I I-endonucleases is selected from I-SceI, I-SceIV and I-PanI sites, does not reasonably provide enablement for any and all endonucleases sites selected from any and all Classes of Group-I intron encoded endonucleases sites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention **commensurate in scope** with these claims.

The scope of instant invention as claimed encompasses any and all endonucleases sites selected from any Class of Group I intron encoded endonuclease sites. At best the specification only discloses endonucleases sites for Class I (I-SceI, I-SceIV, I-PanI) and Class II (I-TevI). The specification even fails to disclose any nucleotide sequences for and Class III (I-PpoI), Class IV (I-TevII) and Class V (I-TevIII) endonucleases (spec. page 27 and fig-6). In addition, the specification clearly teaches that that Class III, IV and V endonuclease sites are not represented by any typical structural motifs (spec. page 27, lines 13-21). Therefore, it is unclear how one skill in the art would use invention as claimed with the knowledge of nucleotide sequence that encodes a particular Class of Group-I intron encoded endonucleases sites. Furthermore, endonucleases of Class I (I-SceI, I-SceIV, I-PanI) are structurally and functionally distinct endonucleases that endonuclease sites which are unique to each enzyme. The art at the time of

filing teaches that Group-I introns form a structural and functional groups of introns with wide spread irregular distribution among very diverse organisms and genetic systems (Dujon Gene 82:91-114, 1989, see abstract). Furthermore, the general knowledge in the art concerning Group I Intron encoded endonuclease does not provide any indication as how the structure of one Class of endonucelases is representative of other classes having concordant or discordant functions (Dujon Gene 82:115,-118 1989. see page 17, table-I). Thus, in view of lack of specific guidance in the specification, the skilled artesian at the time of filing would be unable to use the claimed invention, without an excessive and undue amount of experimentation.

In addition, the scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). The courts have clearly stated that: "A specification did not disclose what is well known in the art. See, e.g., Hybritech Inc. V. Monoclonal Antibodies, Inc., 802 F. 2d 1367, 1385, 231 USPQ 81, 94(Fed. Cir. 1986). However, that general off-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific material or of any of the conditions under which a process can be carried out, undue experimentation is required: there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. *It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".* Genentech Inc. V. Novo Nordisk A/s, 42 USPQ2d 1005 (CAFC 1997). In instant case without sufficient guidance, determination of any and all Group-I endonucelase sites is not considered routine and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See Ex parte Singh, 17 USPQ2d 1714 (BPAI 1991). Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

S. Kaushal
Patent examiner

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